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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HUMAN GENOME SCIENCES INC
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EXAMINER

ZARA, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

08/14/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/348,815

Applicant(s)

LI, HAODONG

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29, 33-36, 39, 40, 43, 44, 47-49, 59-67, 72-74, 77, 78, 81, 82, 85 and 86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29, 33-36, 39, 40, 43, 44, 47-49, 59-67, 72-74, 77, 78, 81, 82, 85 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

File

Application/Control Number: 09/348,815

Page 2

Art Unit: 1635

DETAILED ACTION

K.T.
8/13

This Office action is in response to the communication filed ^{May 31,} ~~June 4,~~ 2001, Paper No. 14.

Claims 21-29, 33-36, 39, 40, 43, 44, 47-49, 59-67, 72-74, 77, 78, 81, 82, 85 and 86 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23, 25, 27, 29, 33, 36, 40, 44, 48, 61, 65, 67, 74, 78, 82 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons set forth in the Office action mailed January 18, 2001, Paper No. 11.

Applicant's arguments filed June 4, 2001 have been fully considered but they are not persuasive. Applicants' assert that the dependent claims listed in the instant rejection, which are drawn to any and/or all sequences which are heterologous to SEQ ID NO: 2, are further limiting than the independent claims from which they depend, which independent claims are drawn to

Art Unit: 1635

specific sequences. Contrary to Applicants' assertions, the dependent claims drawn to any and/or all sequences which are heterologous sequences of the sequences which are claimed in the independent claims do not further limit the sequences, but expand them very broadly.

Claims 21, 23, 25, 27-29, 33-36, 43, 44, 47, 48, 59, 61, 63-67, 72-74, 77, 78, 81, 82, 85 and 86 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed January 18, 2001, Paper No. 11.

Applicant's arguments filed June 4, 2001 have been fully considered but they are not persuasive. Applicants' assert that adequate written description has been provided for the claimed invention comprising heterologous sequences of SEQ ID NO: 2 and fragments thereof, whereby such heterologous sequences and fragments stimulate cellular proliferation. Contrary to Applicants' assertions, no evidence has been provided in the instant specification whereby a representative number of species within the claimed genus comprising homologues or fragments of SEQ ID NO: 2 have been disclosed such that concise structural features which distinguish fragments or homologues which stimulate cellular proliferation from those which do not stimulate cellular proliferation have been provided. Therefore, one of skill in the art would reasonably conclude that Applicants were not in possession of the claimed genus at the time the invention was made.

Applicants' assert that a representative number of species within the claimed genus have been disclosed in the instant specification. Contrary to Applicants' assertion, no evidence has

Art Unit: 1635

been provided in the instant specification for which members of the genus comprising homologues or fragments of SEQ ID NO: 2 comprise stimulation for cellular proliferation in vitro or in vivo. A disclosure of a single sequence does not constitute adequate disclosure of a representative number of species for the claimed genus. Furthermore, no evidence has been provided in the instant specification for any activity for the entire coding region of SEQ ID NO: 2, nor for any homologues or fragments thereof. Applicants have provided a written disclosure which was published subsequent to the claimed priority date of the instant application whereby stimulation for cellular proliferation and migration have been documented for the full length coding sequence of Cyr61 (i.e. SEQ ID NO: 2) (See Xie et al, provided as Exhibit A in the communication filed by Applicants on June 4, 2001, Paper No. 14: last paragraph on page 14,191-second to last paragraph on page 14,192). Therefore one of skill in the art would reasonably conclude that Applicants' were not enabled for the claimed genus comprising homologues and fragments of SEQ ID NO: 2, whereby such homologues or fragments elicited stimulation for cellular proliferation, at the time the invention was made.

New Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1635

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22, 24, 26, 60 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-40, 48-50 and 52 of U.S. Patent No. 5,945,300. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to isolated polypeptides comprising sequences comprising SEQ ID NO: 2 and subsequences of SEQ ID NO: 2. Claims 37-40, 48-50 and 52 of U.S. Patent No. 5,945,300 are drawn to a broader scope than claims 22, 24, 26, 60 and 62 of the instant application, which former scope comprises the polypeptide comprising SEQ ID NO: 2, as well as subsequences within this polypeptide (amino acids -24 to 351 of SEQ ID NO: 2). Claims 22, 24, 26, 60 and 62 of the instant application are drawn to a narrower scope, comprising subsequences of SEQ ID NO: 2 (amino acids 1 to 381 of SEQ ID NO: 2). Therefore, because claims 22, 24, 26, 60 and 62 of the instant application and claims 37-40, 48-50 and 52 of U.S. Patent No. 5,945,300 are all drawn to the same polypeptide comprising SEQ ID NO: 2, or portions thereof, they are overlapping in scope and therefore claims 22, 24, 26, 60 and 62 of the instant application are obvious over the previously allowed claims 37-40, 48-50 and 52 of U.S. Patent No. 5,945,300.

Art Unit: 1635

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 27, 29, 33, 36, 40, 44, 48, 61, 63, 65, 67, 74, 78, 82 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the claims cannot be determined in these claims because they contain the term "heterologous" with respect to the polypeptide SEQ ID NO: 2. (i.e. Does this refer to wobble nucleotide sequences encoding the polypeptide of SEQ ID NO: 2, as well as any and/or all variations of the polypeptide SEQ ID NO: 2?). Clarification must be provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 25, 27, 29, 33, 36, 40, 44, 48, 61, 63, 65, 67, 74, 78, 82 and 86 are rejected under 35 U.S.C. 102(b) as being by Purchio et al.

Art Unit: 1635

Purchio et al (EP 0 495674A2, previously cited in the Office action mailed January 18, 2001, Paper No. 11) teach isolated polypeptides comprising sequences which are heterologous to SEQ ID NO: 2 and the subsequences thereof. (See Purchio et al: figure 1, SEQ ID NO: 2, claim 2).

Art Unit: 1635


Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

August 13, 2001



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SUPERVISORY PATENT EXAMINER
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